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July 8, 1996

Regulatory Branch  
Division of Programs and Enforcement Policy  
Office of Special Nutritionals (HFS-456)  
Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 C Street, S.W.  
Washington, DC 20204

Attn: Margaret Binzer  
Consumer Safety Officer

Re: GENISTA™: Statements of Nutritional Support

Ladies/Gentlemen:

Pursuant to Section 6 of the Dietary Supplement Health and Education Act of 1994, 21 U.S.C. § 343(r)(6), this is to notify the Food and Drug Administration that our client Cartilage Technologies, Inc. of Elmsford, New York has within the last 30 days begun marketing its GENISTA™ brand dietary supplement containing pure soya protein isolate, with the following labeling statements that describe the role of this nutrient intended to affect human body structure or function, or that describe general well being from consumption of this nutrient:

"Lowers blood cholesterol levels in conjunction with a low cholesterol diet."

"Soya beans are a rich source of nutrients and natural substances with health promoting properties."

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"The multiple health benefits of soya have been clear for thousands of years. In the last decade, thousands of publications have identified the healthful properties of soya beans."

"You can now enjoy the advantage of modern scientific research on the very powerful benefits of a diet high in soya's health-enhancing properties with Genista brand soya protein isolate containing isoflavones."

"An ideal combination of high quality soya protein and isoflavones to lower blood cholesterol levels."

"Considerable interest has focused on the beneficial health effects of soya protein isolates containing isoflavones (especially genistein)."

Sincerely yours,



Charles J. Raubicheck

CJR/jbh

cc: Cartilage Technologies, Inc.